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Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability MDL NO. 15-02641-PHX-DGC
Litigation

This Document Relates to:

JOANNA DARWACTOR,

Plaintiff,

Case No. CV-15-02308-PHX-DGC

v.

C. R. BARD, INC., a foreign corporation,
and BARD PERIPHERAL VASCULAR,
INC., an Arizona corporation,

Defendants.

**DEFENDANTS C. R. BARD, INC. AND
BARD PERIPHERAL VASCULAR,
INC.'S ANSWER AND AFFIRMATIVE
DEFENSES AND DEMAND FOR
TRIAL BY JURY**

1 Defendants C. R. Bard, Inc. (“Bard”) and Bard Peripheral Vascular, Inc. (“BPV”)
2 (Bard and BPV are collectively “Defendants”) answer the Complaint (“Plaintiff’s
3 Complaint”) of Plaintiff Joanna Darwactor (“Plaintiff”) as follows:

4 1. Defendants are without knowledge or information sufficient to form a belief as
5 to the truth of the allegations regarding the citizenship and residency of Plaintiff and, on that
6 basis, deny them. Defendants deny the remaining allegations contained in Paragraph 1 of
7 Plaintiff’s Complaint.

8 2. Defendants are without knowledge or information sufficient to form a belief as
9 to the truth of the allegations regarding the trade name of any inferior vena cava filter
10 implanted in Plaintiff and, on that basis, deny them. Defendants deny the remaining
11 allegations contained in Paragraph 2 of Plaintiff’s Complaint.

12 3. Defendants deny the allegations contained in Paragraph 3 of Plaintiff’s
13 Complaint.

14 4. Defendants admit that Bard is a New Jersey Corporation and that Bard is
15 authorized to do business, and does business, in the state of South Carolina, including
16 Florence, South Carolina. Defendants admit that Bard owns a facility where vena cava filters
17 are manufactured, including under the trademark Eclipse™ Filters. Defendants deny any
18 remaining allegations contained in Paragraph 4 of Plaintiff’s Complaint.

19 5. Defendants admit that BPV is an Arizona Corporation and that BPV is
20 authorized to do business, and does business, in the state of South Carolina, including
21 Florence, South Carolina. Defendants further admit that BPV is a wholly owned subsidiary of
22 Bard. Defendants also admit that BPV designs, sells, markets, and distributes inferior vena
23 cava filters and that BPV has designed, sold, marketed, and distributed filters under the
24 trademark Eclipse™ Filter System. Defendants deny any remaining allegations contained in
25 Paragraph 5 of Plaintiff’s Complaint.

6. Paragraph 6 of Plaintiff's Complaint does not contain any factual allegations, requiring no response by Defendants. However, to the extent Paragraph 6 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

JURISDICTION AND VENUE

7. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, jurisdiction appears to be proper in the United States District Court for the District of South Carolina. However, Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever.

8. Defendants do not dispute that, based on the allegations contained in Plaintiff's Complaint, which have not been and could not have been confirmed by Defendants, Plaintiff seeks damages in excess of the jurisdictional threshold for this Court. However, Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever.

9. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, jurisdiction appears to be proper in the United States District Court for the District of South Carolina. However, Defendants deny that either Bard or BPV resides in the District of South Carolina.

GENERAL FACTUAL ALLEGATIONS

10. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants do not dispute that Plaintiff brings this action against them, but Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever. Defendants deny the remaining allegations contained in Paragraph 10 of Plaintiff's Complaint.

11. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Eclipse™ Filter System were manufactured

1 at that facility. Defendants further admit that BPV designs, sells, markets, and distributes
2 inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under
3 the trademark Eclipse™ Filter System. Defendants further admit that inferior vena cava
4 filters, including the Eclipse™ Filter System, are intended to prevent injury or death resulting
5 from venous thrombosis and pulmonary embolism. Defendants deny any remaining
6 allegations contained in Paragraph 11 of Plaintiff's Complaint.

7 12. Defendants deny the allegations contained in Paragraph 12 of Plaintiff's
8 Complaint, including all sub-parts thereof.

9 13. Defendants lack knowledge or information sufficient to admit or deny the
10 allegation regarding the time frame when inferior vena cava filters were first introduced on
11 the market or the identity of manufacturers of inferior vena cava filters. Defendants deny any
12 remaining allegations of Paragraph 13 of Plaintiff's Complaint.

13 14. Defendants admit that inferior vena cava filters are intended to prevent injury or
14 death resulting from venous thrombosis and pulmonary embolism. Defendants further admit
15 that inferior vena cava filters may be designed for permanent placement, temporary
16 placement, or both. Defendants deny any remaining allegations of Paragraph 14 of Plaintiff's
17 Complaint.

18 15. Defendants admit that the inferior vena cava is a large vein that receives blood
19 from the lower regions of the body and delivers it to the right atrium of the heart. Defendants
20 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to
21 human health, including sometimes death. Defendants deny any remaining allegations of
22 Paragraph 15 of Plaintiff's Complaint.

23 16. Defendants admit that certain people are at an increased risk for the
24 development of deep vein thrombosis and pulmonary embolus, but lack sufficient information
25 to admit or deny the allegations regarding the various treatments recommended by physicians
26 to treat such risk and, therefore, deny them. Defendants deny any remaining allegations of
27 Paragraph 16 of Plaintiff's Complaint.

1 17. Defendants admit that certain people are at an increased risk for the
2 development of deep vein thrombosis and pulmonary embolus, but lack sufficient information
3 to admit or deny the allegations regarding the various treatments recommended by physicians
4 to treat such risk and, therefore, deny them. Defendants deny any remaining allegations of
5 Paragraph 17 of Plaintiff's Complaint.

6 18. Defendants lack knowledge or information or information sufficient to form a
7 belief as to the truth of the allegation regarding the time frame when inferior vena cava filters
8 were first introduced on the market. Defendants also lack knowledge or information sufficient
9 to form a belief as to the truth of the allegation regarding the time frame when optional or
10 retrievable filters came to be marketed or the other allegations regarding optional or
11 retrievable filters marketed by other manufacturers. Defendants deny any remaining
12 allegations contained in Paragraph 18 of Plaintiff's Complaint.

13 19. Defendants admit that Bard has distributed the Simon Nitinol Filter in the
14 United States since at least 1992 and that the Simon Nitinol Filter is indicated for permanent
15 use. Defendants admit that, as part of their continuing efforts to constantly evaluate the
16 medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
17 continually striving to improve the life-saving performance of those devices. The Recovery®
18 Filter was developed in furtherance of those efforts. Defendants deny the remaining
19 allegations contained in Paragraph 19 of Plaintiff's Complaint, as stated.

20 20. Defendants admit that the Recovery® Filter was cleared by the FDA for
21 permanent placement on November 27, 2002, pursuant to an application submitted under
22 Section 510(k) of the Food, Drug and Cosmetic Act. The allegations pertaining to the
23 requirements of Section 510(k) are legal conclusions of law to which no answer is required.
24 To the extent a response is required, Defendants deny the allegations and characterizations of
25 the FDA approval and clearance process. Defendants deny any remaining allegations
26 contained in Paragraph 20 of Plaintiff's Complaint.

1 21. Defendants admit that the Recovery® Filter was cleared by the FDA for
2 retrievable placement on July 25, 2003, pursuant to an application submitted under Section
3 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations
4 contained in Paragraph 21 of Plaintiff's Complaint.

5 22. Defendants admit that the Recovery® Filter consists of twelve shape-memory
6 Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the
7 twelve wires form two levels of filtration for emboli: the legs provide the lower level of
8 filtration, and the arms provide the upper level of filtration. Defendants deny any remaining
9 allegations contained in Paragraph 22 of Plaintiff's Complaint.

10 23. Defendants admit that a nickel-titanium alloy named Nitinol is used in the
11 manufacture of the Recovery® Filter and further admit that Nitinol contains shape memory.
12 However, to the extent Paragraph 23 purports to cast liability either directly or indirectly
13 upon Defendants, said Paragraph is expressly denied.

14 24. Defendants admit that the Recovery® Filter was designed to be inserted
15 endovascularly. Defendants further admit that the Recovery® Filter is designed to be
16 delivered via an introducer sheath, which is included in the delivery system for the device.
17 Defendants deny any remaining allegations of Paragraph 24 of Plaintiff's Complaint.

18 25. Defendants deny the allegations contained in Paragraph 25 of Plaintiff's
19 Complaint.

20 26. Defendants deny the allegations contained in Paragraph 26 of Plaintiff's
21 Complaint.

22 27. Defendants deny the allegations contained in Paragraph 27 of Plaintiff's
23 Complaint.

24 28. Defendants deny the allegations contained in Paragraph 28 of Plaintiff's
25 Complaint.

26 29. Defendants deny the allegations contained in Paragraph 29 of Plaintiff's
27 Complaint.

1 30. Defendants deny the allegations contained in Paragraph 30 of Plaintiff's
2 Complaint, including all sub-parts thereof.

3 31. Defendants deny the allegations contained in Paragraph 31 of Plaintiff's
4 Complaint, including all sub-parts thereof.

5 32. Defendants deny the allegations contained in Paragraph 32 of Plaintiff's
6 Complaint.

7 33. Defendants deny the allegations contained in Paragraph 33 of Plaintiff's
8 Complaint.

9 34. Defendants deny the allegations contained in Paragraph 34 of Plaintiff's
10 Complaint, including all sub-parts thereof.

11 35. Defendants deny the allegations contained in Paragraph 35 of Plaintiff's
12 Complaint.

13 36. Defendants deny the allegations contained in Paragraph 36 of Plaintiff's
14 Complaint.

15 37. Defendants deny the allegations contained in Paragraph 37 of Plaintiff's
16 Complaint.

17 38. Defendants deny the allegations contained in Paragraph 38 of Plaintiff's
18 Complaint.

19 39. Defendants deny the allegations contained in Paragraph 39 of Plaintiff's
20 Complaint.

21 40. Defendants deny the allegations contained in Paragraph 40 of Plaintiff's
22 Complaint.

23 41. Defendants deny the allegations contained in Paragraph 41 of Plaintiff's
24 Complaint, including all sub-parts thereof.

25 42. Defendants deny the allegations contained in Paragraph 42 of Plaintiff's
26 Complaint, including all sub-parts thereof.

1 43. Defendants admit that, as part of their continuing efforts to constantly evaluate
2 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
3 continually striving to improve the life-saving performance of those devices. Defendants
4 deny the remaining allegations contained in Paragraph 43 of Plaintiff's Complaint.

5 44. Defendants admit that, as part of their continuing efforts to constantly evaluate
6 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
7 continually striving to improve the life-saving performance of those devices. Defendants deny
8 any remaining allegations contained in Paragraph 44 of Plaintiff's Complaint.

9 45. Defendants deny the allegations contained in Paragraph 45 of Plaintiff's
10 Complaint, as stated.

11 46. Defendants deny the allegations contained in Paragraph 46 of Plaintiff's
12 Complaint.

13 47. Defendants deny the allegations contained in Paragraph 47 of Plaintiff's
14 Complaint.

15 48. Defendants deny the allegations contained in Paragraph 48 of Plaintiff's
16 Complaint.

17 49. Defendants deny the allegations contained in Paragraph 49 of Plaintiff's
18 Complaint.

19 50. Defendants deny the allegations contained in Paragraph 50 of Plaintiff's
20 Complaint.

21 51. Defendants deny the allegations contained in Paragraph 51 of Plaintiff's
22 Complaint.

23 52. Defendants deny the allegations contained in Paragraph 52 of Plaintiff's
24 Complaint.

25 53. Defendants deny the allegations contained in Paragraph 53 of Plaintiff's
26 Complaint.

1 54. Defendants deny the allegations contained in Paragraph 54 of Plaintiff's
2 Complaint.

3 55. Defendants deny the allegations contained in Paragraph 55 of Plaintiff's
4 Complaint.

5 56. Defendants deny the allegations contained in Paragraph 56 of Plaintiff's
6 Complaint.

7 57. Defendants deny the allegations contained in Paragraph 57 of Plaintiff's
8 Complaint.

9 58. Defendants admit that the G2® Filter was cleared by the FDA in August 2005
10 pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic
11 Act. Defendants deny any remaining allegations contained in Paragraph 58 of Plaintiff's
12 Complaint.

13 59. Defendants admit that the G2® Filter was cleared by the United States Food and
14 Drug Administration for retrievable placement on January 15, 2008. Defendants deny any
15 remaining allegations contained in Paragraph 59 of Plaintiff's Complaint,

16 60. Defendants admit that, as part of their continuing efforts to constantly evaluate
17 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
18 continually striving to improve the life-saving performance of those devices. Defendants deny
19 the remaining allegations contained in Paragraph 60 of Plaintiff's Complaint.

20 61. Defendants deny the allegations contained in Paragraph 61 of Plaintiff's
21 Complaint.

22 62. Defendants deny the allegations contained in Paragraph 62 of Plaintiff's
23 Complaint.

24 63. Defendants deny the allegations contained in Paragraph 63 of Plaintiff's
25 Complaint, including all sub-parts thereof, as stated. By way of further answer, Defendants
26 admit that there are various well-documented complications that may occur as a result of the
27 fracture, tilt, perforation, and/or migration of any inferior vena cava filter, and that it is well-
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1 documented that many instances of filter fracture, tilt, perforation, and/or migration result in
2 no complications whatsoever, but, rather, are completely asymptomatic. Further, Defendants
3 state that there are incidents related to the occurrence of known complications associated with
4 every manufacturer of inferior vena cava filters.

5 64. Defendants admit that there are various well-documented complications that
6 may occur as the result of the fracture of any inferior vena cava filter. Defendants state that
7 there are incidents related to the occurrence of known complications associated with every
8 manufacturer of inferior vena cava filters. By way of further response, Defendants state that
9 information available in the public domain, including the FDA MAUDE database, is not a
10 comprehensive analysis of all instances of such complications. Defendants deny the
11 remaining allegations contained in Paragraph 64 of Plaintiff's Complaint.

12 65. Defendants admit that there are various well-documented complications that
13 may occur as the result of the fracture of any inferior vena cava filter. Defendants state that
14 there are incidents related to the occurrence of known complications associated with every
15 manufacturer of inferior vena cava filters. By way of further response, Defendants state that
16 information available in the public domain, including the FDA MAUDE database, is not a
17 comprehensive analysis of all instances of such complications. Defendants deny the
18 remaining allegations contained in Paragraph 65 of Plaintiff's Complaint.

19 66. Defendants admit the G2® Express Filter System was cleared by the United
20 States Food and Drug Administration pursuant to an application submitted under Section
21 510(k) of the Food, Drug and Cosmetic Act in 2008. Defendants further admit that the G2®
22 and G2® Express Filters are similarly designed, except that the G2® Express Filter was
23 equipped with a snarable "hook" to allow retrievable via a snare device. Defendants deny any
24 remaining allegations contained in Paragraph 66 of Plaintiff's Complaint.

25 67. Defendants admit the Eclipse™ Filter System was cleared by the United States
26 Food and Drug Administration pursuant to an application submitted under Section 510(k) of
27
28

1 the Food, Drug and Cosmetic Act in 2010. Defendants deny any remaining allegations
2 contained in Paragraph 67 of Plaintiff's Complaint.

3 68. Defendants admit that, as part of their continuing efforts to constantly evaluate
4 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
5 continually striving to improve the life-saving performance of those devices. The Eclipse™
6 Filter, which is constructed of Nitinol and electropolished, was developed in furtherance of
7 those efforts. Defendants deny any remaining allegations contained in Paragraph 68 of
8 Plaintiff's Complaint, including any allegations contained in Footnote 2.

9 69. Defendants deny the allegations contained in Paragraph 69 of Plaintiff's
10 Complaint.

11 70. Defendants deny the allegations contained in Paragraph 70 of Plaintiff's
12 Complaint.

13 71. Defendants deny the allegations contained in Paragraph 71 of Plaintiff's
14 Complaint, including all sub-parts thereof.

15 72. Defendants deny the allegations contained in Paragraph 72 of Plaintiff's
16 Complaint.

17 73. Defendants deny the allegations contained in Paragraph 73 of Plaintiff's
18 Complaint.

19 74. Defendants deny the allegations contained in Paragraph 74 of Plaintiff's
20 Complaint.

21 75. Defendants deny the allegations contained in Paragraph 75 of Plaintiff's
22 Complaint, including all sub-parts thereof.

23 76. Defendants deny the allegations contained in Paragraph 76 of Plaintiff's
24 Complaint.

25 77. Defendants deny the allegations contained in Paragraph 77 of Plaintiff's
26 Complaint.

1 78. Defendants are without knowledge or information sufficient to form a belief as
2 to the truth of the allegations regarding the trade name of any inferior vena cava filter
3 implanted in Plaintiff and, therefore, deny them. Defendants deny the allegations contained in
4 Paragraph 78 of Plaintiff's Complaint.

5 79. Defendants admit that Bard owns a facility where vena cava filters are
6 manufactured, including under the trademark Eclipse™ Filters. Defendants also admit that
7 BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has
8 designed, sold, marketed, and distributed filters under the trademark Eclipse™ Filter System.
9 Defendants deny any remaining allegations contained in Paragraph 79 of Plaintiff's
10 Complaint.

11 80. Defendants deny the allegations contained in Paragraph 80 of Plaintiff's
12 Complaint.

13 81. Defendants incorporate by reference their responses to Paragraphs 1-80 of
14 Plaintiff's Complaint as if fully set forth herein.

15 82. Defendants deny the allegations contained in Paragraph 82 of Plaintiff's
16 Complaint.

17 83. Defendants deny the allegations contained in Paragraph 83 of Plaintiff's
18 Complaint.

19 84. Defendants deny the allegations contained in Paragraph 84 of Plaintiff's
20 Complaint.

21 85. Defendants deny the allegations contained in Paragraph 85 of Plaintiff's
22 Complaint.

23 86. Defendants deny the allegations contained in Paragraph 86 of Plaintiff's
24 Complaint.

25 87. Defendants deny the allegations contained in Paragraph 87 of Plaintiff's
26 Complaint.

1 97. Defendants deny the allegations contained in Paragraph 97 of Plaintiff's
2 Complaint, including all sub-parts thereof.

3 98. Defendants deny the allegations contained in Paragraph 98 of Plaintiff's
4 Complaint.

5 99. Defendants deny the allegations contained in Paragraph 99 of Plaintiff's
6 Complaint.

7 100. Defendants deny the allegations contained in Paragraph 100 of Plaintiff's
8 Complaint, including all sub-parts thereof.

9 101. Defendants deny the allegations contained in Paragraph 101 of Plaintiff's
10 Complaint.

11 **COUNT II**

12 **NEGLIGENT FAILURE TO WARN**

13 102. Defendants incorporate by reference their responses to Paragraphs 1-101 of
14 Plaintiff's Complaint as if fully set forth herein.

15 103. Defendants admit that Bard owns a facility where vena cava filters are
16 manufactured, including under the trademark Eclipse™ Filter System. Defendants further
17 admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV
18 has designed, sold, marketed, and distributed filters under the trademark Eclipse™ Filter
19 System. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations regarding the trade name of any inferior vena cava filter implanted in
21 Plaintiff and, therefore, deny them. Defendants deny any remaining allegations contained in
22 Paragraph 103 of Plaintiff's Complaint.

23 104. Defendants deny the allegations contained in Paragraph 104 of Plaintiff's
24 Complaint.

25 105. The allegations contained in Paragraph 105 of Plaintiff's Complaint regarding
26 Defendants' duty are conclusions of law, to which no response is required. To the extent a
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1 response is required, Defendants deny those allegations. Defendants deny the remaining
2 allegations contained in Paragraph 105 of Plaintiff's Complaint.

3 106. Defendants deny the allegations contained in Paragraph 106 of Plaintiff's
4 Complaint.

5 107. Defendants deny the allegations contained in Paragraph 107 of Plaintiff's
6 Complaint.

7 108. Defendants deny the allegations contained in Paragraph 108 of Plaintiff's
8 Complaint.

9 109. Defendants deny the allegations contained in Paragraph 109 of Plaintiff's
10 Complaint.

11 110. Defendants deny the allegations contained in Paragraph 110 of Plaintiff's
12 Complaint.

13 111. Defendants deny the allegations contained in Paragraph 111 of Plaintiff's
14 Complaint.

15 112. Defendants deny the allegations contained in Paragraph 112 of Plaintiff's
16 Complaint.

17 **COUNT III**

18 **STRICT LIABILITY FAILURE TO WARN**

19 113. Defendants incorporate by reference their responses to Paragraphs 1-112 of
20 Plaintiff's Complaint as if fully set forth herein.

21 114. Defendants admit that Bard owns a facility where vena cava filters are
22 manufactured, including under the trademarks Eclipse™ Filter System. Defendants further
23 admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV
24 has designed, sold, marketed, and distributed filters under the trademarks Eclipse™ Filter
25 System. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations regarding the trade name of any inferior vena cava filter implanted in
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1 Plaintiff and, therefore, deny them. Defendants deny any remaining allegations contained in
2 Paragraph 114 of Plaintiff's Complaint.

3 115. The allegations contained in Paragraph 115 of Plaintiff's Complaint regarding
4 Defendants' duty are conclusions of law, to which no response is required. To the extent a
5 response is required, Defendants deny those allegations. Defendants deny any remaining
6 allegations contained in Paragraph 115 of Plaintiff's Complaint.

7 116. Defendants deny the allegations contained in Paragraph 116 of Plaintiff's
8 Complaint.

9 117. Defendants deny the allegations contained in Paragraph 117 of Plaintiff's
10 Complaint.

11 118. Defendants deny the allegations contained in Paragraph 118 of Plaintiff's
12 Complaint.

13 119. Defendants deny the allegations contained in Paragraph 119 of Plaintiff's
14 Complaint.

15 120. Defendants deny the allegations contained in Paragraph 120 of Plaintiff's
16 Complaint.

17 121. Defendants deny the allegations contained in Paragraph 121 of Plaintiff's
18 Complaint.

19 122. Defendants deny the allegations contained in Paragraph 122 of Plaintiff's
20 Complaint.

21 **COUNT IV**

22 **STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

23 123. Defendants incorporate by reference their responses to Paragraphs 1-122 of
24 Plaintiff's Complaint as if fully set forth herein.

25 124. By way of further response, Defendants admit that Bard owns a facility where
26 vena cava filters are manufactured and that filters under the trademark Eclipse™ Filter
27 System were manufactured at that facility. Defendants further admit that BPV designs, sells,
28

1 markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and
 2 distributed filters under the trademark Eclipse™ Filter System. Defendants are without
 3 knowledge or information sufficient to form a belief as to the truth of the allegations
 4 regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that
 5 basis, deny them. Defendants deny any remaining allegations contained in Paragraph 124 of
 6 Plaintiff's Complaint.

7 125. Defendants deny the allegations contained in Paragraph 125 of Plaintiff's
 8 Complaint.

9 126. Defendants deny the allegations contained in Paragraph 126 of Plaintiff's
 10 Complaint.

11 127. Defendants deny the allegations contained in Paragraph 127 of Plaintiff's
 12 Complaint.

13 128. Defendants deny the allegations contained in Paragraph 128 of Plaintiff's
 14 Complaint.

15 129. Defendants deny the allegations contained in Paragraph 129 of Plaintiff's
 16 Complaint.

17 130. Defendants deny the allegations contained in Paragraph 130 of Plaintiff's
 18 Complaint.

19 **COUNT V**

20 **STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

21 131. Defendants incorporate by reference their responses to Paragraphs 1-130 of
 22 Plaintiff's Complaint as if fully set forth herein.

23 132. Defendants deny that the Eclipse™ Filter is unreasonably dangerous or
 24 defective in any manner. Defendants are without knowledge or information sufficient to form
 25 a belief as to the truth of the allegations regarding the trade name of any inferior vena cava
 26 filter implanted in Plaintiff and, on that basis, deny them. By way of further response,
 27 Defendants admit that Bard owns a facility where vena cava filters are manufactured and that
 28

1 filters under the trademark Eclipse™ Filter System were manufactured at that facility.
 2 Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava
 3 filters and that BPV designed, sold, marketed, and distributed filters under the trademark
 4 Eclipse™ Filter System. Defendants deny the remaining allegations contained in
 5 Paragraph 132 of Plaintiff's Complaint.

6 133. Defendants deny the allegations contained in Paragraph 133 of Plaintiff's
 7 Complaint.

8 134. Defendants deny the allegations contained in Paragraph 134 of Plaintiff's
 9 Complaint.

10 135. Defendants deny the allegations contained in Paragraph 135 of Plaintiff's
 11 Complaint.

12 136. Defendants deny the allegations contained in Paragraph 136 of Plaintiff's
 13 Complaint.

14 **COUNT VI**

15 **BREACH OF EXPRESS WARRANTY OF MERCHANTABILITY**

16 137. Defendants incorporate by reference their responses to Paragraphs 1-136 of
 17 Plaintiff's Complaint as if fully set forth herein.

18 138. Defendants admit that Bard owns a facility where vena cava filters are
 19 manufactured and that filters under the trademark Eclipse™ Filter System were manufactured
 20 at that facility. Defendants further admit that BPV designs, sells, markets, and distributes
 21 inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under
 22 the trademark Eclipse™ Filter System. Defendants deny any remaining allegations contained
 23 in Paragraph 138 of Plaintiff's Complaint.

24 139. Defendants deny the allegations contained in Paragraph 139 of Plaintiff's
 25 Complaint.

1 113.¹ Defendants deny the allegations contained in Paragraph 113 of Plaintiff's
2 Complaint.

3 114. Defendants deny the allegations contained in Paragraph 114 of Plaintiff's
4 Complaint.

5 115. Defendants deny the allegations contained in Paragraph 115 of Plaintiff's
6 Complaint.

7 116. Defendants deny the allegations contained in Paragraph 116 of Plaintiff's
8 Complaint, including all subparts thereof.

9 117. Defendants deny the allegations contained in Paragraph 117 of Plaintiff's
10 Complaint.

11 118. Defendants deny the allegations contained in Paragraph 118 of Plaintiff's
12 Complaint.

13 119. Defendants deny the allegations contained in Paragraph 119 of Plaintiff's
14 Complaint.

15 120. Defendants deny the allegations contained in Paragraph 120 of Plaintiff's
16 Complaint.

17 **COUNT VII**

18 **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

19 121. Defendants incorporate by reference their responses to Paragraphs 1-120 of
20 Plaintiff's Complaint as if fully set forth herein.

21 122. Defendants admit that Bard owns a facility where vena cava filters are
22 manufactured and that filters under the trademarks Recovery®, G2®, and Eclipse™ Filter
23 Systems were manufactured at that facility. Defendants further admit that BPV designs, sells,
24 markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and
25

26 ¹ Defendants note that Plaintiff's Complaint erroneously begins renumbering all Paragraphs
27 subsequent to Paragraph 139 as Paragraphs 113, *et seq.* For the Court's ease, and for ease
28 of reference, Defendants will refer to these erroneously labeled paragraphs by the manner
in which they are identified in the Plaintiff's Complaint.

distributed filters under the trademarks Recovery®, G2®, and Eclipse™ Filter Systems. Defendants deny any remaining allegations contained in Paragraph 122 of Plaintiff's Complaint.

123. Defendants deny the allegations contained in Paragraph 123 of Plaintiff's Complaint.

124. Defendants deny the allegations contained in Paragraph 124 of Plaintiff's Complaint.

125. Defendants deny the allegations contained in Paragraph 125 of Plaintiff's Complaint.

126. Defendants deny the allegations contained in Paragraph 126 of Plaintiff's Complaint, including all sub-parts thereof.

127. Defendants deny the allegations contained in Paragraph 127 of Plaintiff's Complaint.

128. Defendants deny the allegations contained in Paragraph 128 of Plaintiff's Complaint.

129. Defendants deny the allegations contained in Paragraph 129 of Plaintiff's Complaint.

130. Defendants deny the allegations contained in Paragraph 130 of Plaintiff's Complaint.

COUNT VIII

BREACH OF IMPLIED WARRANTY OF FITNESS

FOR A PARTICULAR PURPOSE

131. Defendants incorporate by reference their responses to Paragraphs 1-130 of Plaintiff's Complaint as if fully set forth herein.

132. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademarks Recovery®, G2®, and Eclipse™ Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells,

1 markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and
2 distributed filters under the trademarks Recovery®, G2®, and Eclipse™ Filter Systems.
3 Defendants deny any remaining allegations contained in Paragraph 132 of Plaintiff's
4 Complaint.

5 133. Defendants deny the allegations contained in Paragraph 133 of Plaintiff's
6 Complaint.

7 134. Defendants deny the allegations contained in Paragraph 134 of Plaintiff's
8 Complaint.

9 135. Defendants deny the allegations contained in Paragraph 135 of Plaintiff's
10 Complaint.

11 136. Defendants deny the allegations contained in Paragraph 136 of Plaintiff's
12 Complaint, including all subparts thereof.

13 137. Defendants deny the allegations contained in Paragraph 137 of Plaintiff's
14 Complaint.

15 138. Defendants deny the allegations contained in Paragraph 138 of Plaintiff's
16 Complaint.

17 139. Defendants deny the allegations contained in Paragraph 139 of Plaintiff's
18 Complaint.

19 140. Defendants deny the allegations contained in Paragraph 140 of Plaintiff's
20 Complaint, including all sub-parts thereof.

21
22 **COUNT IX**

23 **FRAUDULENT CONCEALMENT**

24 141. Defendants incorporate by reference their responses to Paragraphs 1-140 of
25 Plaintiff's Complaint as if fully set forth herein.

26 142. Defendants deny the allegations contained in Paragraph 142 of Plaintiff's
27 Complaint.

1 143. Defendants deny the allegations contained in Paragraph 143 of Plaintiff's
2 Complaint.

3 144. Defendants deny the allegations contained in Paragraph 144 of Plaintiff's
4 Complaint.

5 145. Defendants deny the allegations contained in Paragraph 145 of Plaintiff's
6 Complaint.

7 146. Defendants deny the allegations contained in Paragraph 146 of Plaintiff's
8 Complaint.

9 147. Defendants deny the allegations contained in Paragraph 147 of Plaintiff's
10 Complaint.

11 **COUNT X**

12 **NEGLIGENT MISREPRESENTATION**

13 148. Defendants incorporate by reference their responses to Paragraphs 1-147 of
14 Plaintiff's Complaint as if fully set forth herein.

15 149. Defendants deny the allegations contained in Paragraph 149 of Plaintiff's
16 Complaint, including all sub-parts thereof.

17 150. Defendants deny the allegations contained in Paragraph 150 of Plaintiff's
18 Complaint.

19 151. Defendants deny the allegations contained in Paragraph 151 of Plaintiff's
20 Complaint.

21 152. Defendants deny the allegations contained in Paragraph 152 of Plaintiff's
22 Complaint.

23 153. Defendants deny the allegations contained in Paragraph 153 of Plaintiff's
24 Complaint.

25 154. Defendants deny the allegations contained in Paragraph 154 of Plaintiff's
26 Complaint.

1 155. Defendants deny the allegations contained in Paragraph 155 of Plaintiff's
2 Complaint.

3 156. Defendants deny the allegations contained in Paragraph 156 of Plaintiff's
4 Complaint.

5 157. Defendants deny the allegations contained in Paragraph 157 of Plaintiff's
6 Complaint.

7 158. Defendants deny the allegations contained in Paragraph 158 of Plaintiff's
8 Complaint.

9 159. Defendants deny the allegations contained in Paragraph 159 of Plaintiff's
10 Complaint.

11 160. Defendants deny the allegations contained in Paragraph 160 of Plaintiff's
12 Complaint.

13 **COUNT XI**

14 **FRAUDULENT MISREPRESENTATION**

15 161. Defendants incorporate by reference their responses to Paragraphs 1-160 of
16 Plaintiff's Complaint as if fully set forth herein.

17 162. Defendants deny the allegations contained in Paragraph 162 of Plaintiff's
18 Complaint, including all sub-parts thereof.

19 163. Defendants deny the allegations contained in Paragraph 163 of Plaintiff's
20 Complaint.

21 164. Defendants deny the allegations contained in Paragraph 164 of Plaintiff's
22 Complaint.

23 165. Defendants deny the allegations contained in Paragraph 165 of Plaintiff's
24 Complaint.

25 166. Defendants deny the allegations contained in Paragraph 166 of Plaintiff's
26 Complaint.

1 167. Defendants deny the allegations contained in Paragraph 167 of Plaintiff's
2 Complaint.

3 168. Defendants deny the allegations contained in Paragraph 168 of Plaintiff's
4 Complaint.

5 169. Defendants deny the allegations contained in Paragraph 169 of Plaintiff's
6 Complaint.

7 170. Defendants deny the allegations contained in Paragraph 170 of Plaintiff's
8 Complaint.

9 171. Defendants deny the allegations contained in Paragraph 171 of Plaintiff's
10 Complaint.

11 172. Defendants deny the allegations contained in Paragraph 172 of Plaintiff's
12 Complaint.

13 **PUNITIVE DAMAGES**

14 173. Defendants incorporate by reference their responses to Paragraphs 1-172 of
15 Plaintiff's Complaint as if fully set forth herein.

16 174. Defendants deny the allegations contained in Paragraph 174 of Plaintiff's
17 Complaint.

18 175. Defendants deny the allegations contained in Paragraph 175 of Plaintiff's
19 Complaint, including all sub-parts thereof.

20 176. Defendants deny the allegations contained in Paragraph 176 of Plaintiff's
21 Complaint.

22 177. Defendants deny the allegations contained in Paragraph 177 of Plaintiff's
23 Complaint.

24 Furthermore, responding to the unnumbered Paragraph, including sub-parts thereof,
25 labeled "PRAYER FOR DAMAGES" and beginning "WHEREFORE," Defendants deny the
26 allegations contained in such Paragraph, including all subparts of such Paragraphs and the
27 subsequent paragraphs corresponding to the Counts listed in Plaintiff's Complaint.
28

Defendants further deny each and every allegation not specifically admitted herein.

DEFENSES

Defendants allege as affirmative defenses the following:

1. Plaintiff's Complaint filed herein fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

2. The sole proximate cause of Plaintiff's damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Defendants were and are in no way liable.

3. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations and/or statute of repose.

4. If Plaintiff has been damaged, which Defendants deny, any recovery by Plaintiff is barred to the extent Plaintiff voluntarily exposed herself to a known risk and/or failed to mitigate her alleged damages. To the extent Plaintiff has failed to mitigate her alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

5. If Plaintiff has been damaged, which Defendants deny, such damages were caused by the negligence or fault of Plaintiff.

6. If Plaintiff has been damaged, which Defendants deny, such damages were caused by the negligence or fault of persons and/or entities for whose conduct Defendants are not legally responsible.

7. The conduct of Defendants and the subject product at all times conformed with the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent federal statutes and regulations. Accordingly, Plaintiff's claims are barred, in whole or in part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

1 8. If Plaintiff has been damaged, which Defendants deny, such damages were
2 caused by unforeseeable, independent, intervening, and/or superseding events for which
3 Defendants are not legally responsible.

4 9. There was no defect in the product at issue with the result that Plaintiff is not
5 entitled to recover against Defendants in this cause.

6 10. If there were any defect in the products – and Defendants deny that there were
7 any defects – nevertheless, there was no causal connection between any alleged defect and
8 the product on the one hand and any damage to Plaintiff on the other with the result that
9 Plaintiff is not entitled to recover against Defendants in this cause.

10 11. Plaintiff's injuries, losses or damages, if any, were caused by or contributed to
11 by other persons or entities that are severally liable for all or part of Plaintiff's alleged
12 injuries, losses or damages. If Defendants are held liable to Plaintiff, which liability is
13 specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification,
14 either in whole or in part, from all persons or entities whose negligence or fault proximately
15 caused or contributed to cause Plaintiff's alleged damages.

16 12. Plaintiff's claims are barred to the extent that the injuries alleged in the
17 Plaintiff's Complaint were caused by the abuse, misuse, abnormal use, or use of the product
18 at issue in a manner not intended by Defendants and over which Defendants had no control.

19 13. Plaintiff's claims are barred to the extent that the injuries alleged in the
20 Plaintiff's Complaint were caused by a substantial change in the product after leaving the
21 possession, custody, and control of Defendants.

22 14. Plaintiff's breach of warranty claims are barred because: (1) Defendants did not
23 make any warranties, express or implied, to Plaintiff; (2) there was a lack of privity between
24 Defendants and Plaintiff; and (3) notice of an alleged breach was not given to the seller or
25 Defendants.

26 15. Plaintiff's claims for breach of implied warranty must fail because the product
27 was not used for its ordinary purpose.
28

1 16. Defendants neither had nor breached any alleged duty to warn with respect to
2 the product, with the result that Plaintiff is not entitled to recover in this cause.

3 17. Plaintiff's claims are barred by Defendants' dissemination of legally adequate
4 warnings and instructions to learned intermediaries.

5 18. At all relevant times, herein, Plaintiff's physicians were in the position of
6 sophisticated purchasers, fully knowledgeable and informed with respect to the risks and
7 benefits of the subject product.

8 19. If Plaintiff has been damaged, which Defendants deny, the actions of persons or
9 entities for whose conduct Defendants are not legally responsible and the independent
10 knowledge of these persons or entities of the risks inherent in the use of the product and other
11 independent causes, constitute an intervening and superseding cause of Plaintiff's alleged
12 damages.

13 20. To the extent that injuries and damages sustained by Plaintiff, as alleged in
14 Plaintiff's Complaint, were caused directly, solely, and proximately by sensitivities, medical
15 conditions, and idiosyncrasies peculiar to Plaintiff not found in the general public, they were
16 unknown, unknowable, or not reasonably foreseeable to Defendants.

17 21. Defendants believe, and upon that ground allege, that Plaintiff was advised of
18 the risks associated with the matters alleged in Plaintiff's Complaint and knowingly and
19 voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed
20 consent, release, waiver, or comparative fault, this conduct bars in whole or in part the
21 damages that Plaintiff seeks to recover herein.

22 22. At all relevant times during which the device at issue was designed, developed,
23 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
24 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
25 information, and instructions, all pursuant to generally recognized prevailing industry
26 standards and state-of-the-art in existence at the time.

1 23. Plaintiff's claims are barred because Plaintiff suffered no injury or damages as a
2 result of the alleged conduct and do not have any right, standing, or competency to maintain
3 claims for damages or other relief.

4 24. Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver,
5 estoppel, and/or laches.

6 25. If Plaintiff suffered any damages or injuries, which is denied, Defendants state
7 that Plaintiff's recovery is barred, in whole or in part, or subject to reduction, under the
8 doctrines of contributory and/or comparative negligence.

9 26. In the further alternative, and only in the event that it is determined that
10 Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to
11 the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff,
12 any other defendants, third-party defendants, or other persons, including any party immune
13 because bankruptcy renders them immune from further litigation, as well as any party, co-
14 defendant, or non-parties with whom Plaintiff has settled or may settle in the future.

15 27. Should Defendants be held liable to Plaintiff, which liability is specifically
16 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff
17 from all collateral sources.

18 28. Plaintiff's claims may be barred, in whole or in part, from seeking recovery
19 against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of
20 claims, and the prohibition on double recovery for the same injury.

21 29. The injuries and damages allegedly sustained by Plaintiff may be due to the
22 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff
23 over which Defendants had no control.

24 30. The conduct of Defendants and all activities with respect to the subject product
25 have been and are under the supervision of the Federal Food and Drug Administration
26 ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief,
27 is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.
28

1 31. Defendants assert any and all defenses, claims, credits, offsets, or remedies
2 provided by the Restatements (Second and Third) of Torts and reserve the right to amend
3 their Answer to file such further pleadings as are necessary to preserve and assert such
4 defenses, claims, credits, offsets, or remedies.

5 32. The device at issue complied with any applicable product safety statute or
6 administrative regulation, and therefore Plaintiff's defective design and warnings-based
7 claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and
8 comments thereto.

9 33. Plaintiff cannot show that any reasonable alternative design would have
10 rendered the Eclipse™ Filter inferior vena cava filter device as alleged in Plaintiff's
11 Complaint to be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f,
12 nor could Defendants have known of any alternative design that may be identified by
13 Plaintiff.

14 34. The device at issue was not sold in a defective condition unreasonably
15 dangerous to the user or consumer, and therefore Plaintiff's claims are barred under the
16 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and
17 comparable provisions of the Restatement (Third) of Torts (Products Liability).

18 35. At all relevant times during which the device at issue was designed, developed,
19 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
20 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
21 information, and instructions, all pursuant to generally recognized prevailing industry
22 standards and state-of-the-art in existence at the time.

23 36. Defendants specifically plead all affirmative defenses under the Uniform
24 Commercial Code ("UCC") now existing or which may arise in the future, including those
25 defenses provided by UCC §§ 2-607 and 2-709.

1 37. Plaintiff's alleged damages, if any, should be apportioned among all parties at
2 fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors
3 Act.

4 38. No act or omission of Defendants was malicious, willful, wanton, reckless, or
5 grossly negligent, and, therefore, any award of punitive damages is barred.

6 39. To the extent the claims asserted in Plaintiff's Complaint are based on a theory
7 providing for liability without proof of defect and proof of causation, the claims violate
8 Defendants' rights under the Constitution of the United States and analogous provisions of
9 the South Carolina Constitution.

10 40. Regarding Plaintiff's demand for punitive damages, Defendants specifically
11 incorporate by reference any and all standards of limitations regarding the determination
12 and/or enforceability of punitive damages awards that arose in the decisions of *BMW of*
13 *No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool*
14 *Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct.
15 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S.
16 June 25, 2008) and their progeny as well as other similar cases under both federal and state
17 law.

18 41. Plaintiff's claims for punitive or exemplary damages violate, and are therefore
19 barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of
20 the United States of America, and similar provisions of the South Carolina Constitution, on
21 grounds including the following:

- 22 (a) it is a violation of the Due Process and Equal Protection Clauses of the
23 Fourteenth Amendment of the United States Constitution to impose punitive
24 damages, which are penal in nature, against a civil defendant upon the plaintiffs
25 satisfying a burden of proof which is less than the "beyond a reasonable doubt"
26 burden of proof required in criminal cases;

- 1 (b) the procedures pursuant to which punitive damages are awarded may result in
2 the award of joint and several judgments against multiple defendants for
3 different alleged acts of wrongdoing, which infringes upon the Due Process and
4 Equal Protection Clauses of the Fourteenth Amendment of the United States
5 Constitution;
- 6 (c) the procedures to which punitive damages are awarded fail to provide a
7 reasonable limit on the amount of the award against Defendants, which thereby
8 violates the Due Process Clause of the Fourteenth Amendment of the United
9 States Constitution;
- 10 (d) the procedures pursuant to which punitive damages are awarded fail to provide
11 specific standards for the amount of the award of punitive damages which
12 thereby violates the Due Process Clause of the Fourteenth Amendment of the
13 United States Constitution;
- 14 (e) the procedures pursuant to which punitive damages are awarded result in the
15 imposition of different penalties for the same or similar acts, and thus violate
16 the Equal Protection Clause of the Fourteenth Amendment of the United States
17 Constitution;
- 18 (f) the procedures pursuant to which punitive damages are awarded permit the
19 imposition of punitive damages in excess of the maximum criminal fine for the
20 same or similar conduct, which thereby infringes upon the Due Process Clause
21 of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the
22 Fourteenth Amendment of the United States Constitution;
- 23 (g) the procedures pursuant to which punitive damages are awarded permit the
24 imposition of excessive fines in violation of the Eighth Amendment of the
25 United States Constitution;
- 26 (h) the award of punitive damages to the plaintiff in this action would constitute a
27 deprivation of property without due process of law; and
28

1 (i) the procedures pursuant to which punitive damages are awarded permit the
2 imposition of an excessive fine and penalty.

3 42. Defendants expressly reserve the right to raise as an affirmative defense that
4 Plaintiff has failed to join all parties necessary for a just adjudication of this action, should
5 discovery reveal the existence of facts to support such defense.

6 43. The design complained of in Plaintiff's Complaint, the alleged defects of the
7 product, and/or any alternative design claimed by Plaintiff were not known and, in the light of
8 the existing, reasonably-available scientific and technological knowledge, could not have
9 been known at the time the product at issue was designed, manufactured, and sold. Any
10 alleged alternative design was not scientifically or technologically feasible or economically
11 practical.

12 44. To the extent Plaintiff's Complaint alleges misrepresentation and fraud, these
13 allegations do not comply with the requisite of particularity under applicable procedural rules
14 and/or law.

15 45. Defendants reserve the right to raise such other affirmative defenses as may be
16 available or apparent during discovery or as may be raised or asserted by other defendants in
17 this case. Defendants have not knowingly or intentionally waived any applicable affirmative
18 defense. If it appears that any affirmative defense is or may be applicable after Defendants
19 have had the opportunity to conduct reasonable discovery in this matter, Defendants will
20 assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

21 **REQUEST FOR JURY TRIAL**

22 Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury
23 on all issues appropriate for jury determination.

24 **WHEREFORE**, Defendants aver that Plaintiff is not entitled to the relief demanded in
25 the Plaintiff's Complaint, and these Defendants, having fully answered, pray that this action
26 against them be dismissed and that they be awarded their costs in defending this action and
27 that they be granted such other and further relief as the Court deems just and appropriate.
28

1 This 4th day of December, 2015.

2
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26 **Attorney for Defendants C. R. Bard, Inc. and**
27 **Bard Peripheral Vascular, Inc.**
28

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on December 4, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

s/Richard B. North, Jr.
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